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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,970	01/24/2001	Olga Bandman	PF-0321-2 DIV	7462

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/769,970	Applicant(s) BANDMAN ET AL.	
	Examin r Karen Cochrane Carlson, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-42* is/are pending in the application.

4a) Of the above claim(s) *22,23 and 33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Invention 2, new Claims 24-32, drawn to polynucleotides encoding DAPK-2 having SEQ ID NO: 2 in Paper No. 6, filed August 21, 2002 is acknowledged. The traversal, as expressed on pages 10-14 of Paper #6, is on the ground(s) that the restriction requirement is effectively al election of species between elements in a Markush group. This is not found persuasive because proper Markush goupls comprise molecules having similar structure and function. In the instant application, while the polynucleotides claimed may encode protein kinases associated with disease, the structure is different between the claimed polynucleotides and their encoding proteins and are therefore patentably distinct regardless of whether these polynucleotides are placed within the same claims.

The requirement is still deemed proper and is therefore made FINAL.

At page 14, Applicants have requested that inventions drawn to the method of using the polynucleotide encoding DAPK-2 be rejoined in accordance with *In re Ochiae*. Those inventions drawn to methods of using the polynucleotide will be rejoined when the product polynucleotide is found to be allowable, with the proviso that these methods be amended to recite the allowed product and be enabled, as set forth in *In re Ochiae*.

Claims 1-21 have been canceled. Claims 22, 23, 24-32 (as drawn to sequences other than SEQ ID NO: 2 or 9), and 33-42 have been withdrawn from further consideration by the Examiner because these claims are directed to non-elected subject matter. Claims 22-32 as drawn to polynucleotides encoding DAPK-2 are currently under examination.

Priority is granted to the filing of SN 08/ 878989, June 19, 1997.

The formal drawings have been approved by the draftsman.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 27-29, and 32 are rejected under the judicially created doctrine of double patenting over claims 1-4 of U. S. Patent No. 5, 817,479 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. See the alignment attached to the reference.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The subject matter of the patent is human kinase homologs, which is the same subject matter of the instant application. Patented SEQ ID NO: 8 and instant SEQ ID NO: 9 share 99.2% identity from nucleotides 340-599 of SEQ ID NO: 9. Therefore, Claim 1 of '479 claims polynucleotides encoding biologically active fragments and immunogenically active fragments of SEQ ID NO: 2 9 and a polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 9 and therefore Claims 24 and 32 are obvious over patent Claim 1. Claim 2 of '479 claims an expression vector comprising SEQ ID NO: 8, and therefore Claim 27 is obvious over patent Claim 2. The host cell of patent Claim 3 renders instant Claim 28 obvious. The method of patent claim 4 renders the method of instant Claim 29 obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 24-32 contain non-elected subject matter and therefore do not particularly point out and distinctly claim the subject matter of the elected invention.

Claim 24 recites "biologically active fragments". This phrase is indefinite because it is not clear what activity the fragments should have.

Claim 24 and 31 are drawn to a polynucleotides that encode a polypeptide that is 90% identical to SEQ ID NO: 2 or that is 90% identical to SEQ ID NO: 1, respectively. The word "identical" is an absolute term, that is, either one item is identical to another or it is not. Applicants may wish to replace "identical" with -- identity – .

Claims 24 and 27 depend from non-elected claims and are therefore indefinite. Further, the subject matter of Claim 22 is a polypeptide, and polypeptides are not known to be a polynucleotide linked to a promoter as set forth in Claim 27. To advance the prosecution, Claim 27 has been taken to depend from Claim 24.

Claim 32 broadens the scope of Claim 31. To advance prosecution, Claim 32 has been taken to be an independent claim, such as " an isolated polynucleotide comprising at least 60 contiguous nucleotides of the polynucleotide set forth in SEQ ID NO: 9 or of a polynucleotide that shares at least 90% identity with SEQ ID NO: 9".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not teach polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2, or biologically active or immunogenically active fragments of SEQ ID NO: 2. The specification does not teach polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function. Without a statement regarding the activity of a polynucleotides encoding a polypeptide have 90% identity to SEQ ID NO: 2, or biologically active or immunogenically active fragments of SEQ ID NO: 2 or of polynucleotides that are 90% identical to SEQ ID NO: 9 and encode a polypeptide having any function one skilled in the art cannot know the metes and bounds of the claimed polynucleotides. For example, the claims encompass inactive and/or antagonist kinases, fragments having non-kinase activity, and the like. Therefore, there is no functional parameter of activity for these polynucleotides and therefore the claims lack written description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 24, 27-29, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young et al. (USP 5, 817,479). See the alignment attached to the reference. The subject matter of the patent is human kinase homologs, which is the same subject matter of the instant application. Patented SEQ ID NO: 8 and instant SEQ ID NO: 9 share 99.2% identity from nucleotides 340-599 of SEQ ID NO: 9. Therefore, Claim 1 of '479 claims polynucleotides encoding biologically active fragments and immunogenically active fragments of SEQ ID NO: 2 9 and a polynucleotide comprising at least 60 contiguous nucleotides of SEQ ID NO: 9 and therefore Claims 24 and 32 are anticipated. Claim 2 of '479 claims an expression vector comprising SEQ ID NO: 8, and therefore Claim 27 is anticipated. The host cell of patent Claim 3 renders instant Claim 28 anticipated. The method of patent claim 4 renders the method of instant Claim 29 anticipated.

Claims 24, 27, 28, and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Hillier et al. (September, 1996; Genome Res. 6(9): 807-828). Only the abstract and alignment of this reference will be provided because the 280,000 ESTs taught therein are referenced to the alignment. See the alignment attached to the reference.

Hillier et al. teach a a polynucleotide sequence that shares 99% identity with nucleotides 988-1561 of SEQ ID NO: 9. Therefore, Hillier et al. teach a polynucleotide encoding biologically active fragments and immunogenically active fragments of SEQ ID NO: 2 (Claim 24). This

polynucleotide comprises at least 60 contiguous nucleotides of SEQ ID NO: 9 (Claim 32). This polynucleotide was placed in vector pT7T3D-Pac (Claim 27) and transformed into E coli host cell DH10B (Claim 28).

Claims 24 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers (January 1996; Genbank Accession G15342). Myers teach a 250 nucleotide sequence that shares 98.8% identity with nucleotides 1310 to 1559 of SEQ ID NO: 9. Therefore, Myer teaches a polynucleotide encoding biologically active fragments and immunogenically active fragments of SEQ ID NO: 2 (Claim 24). This polynucleotide comprises at least 60 contiguous nucleotides of SEQ ID NO: 9 (Claim 32).

Claims 24, 27, 28, 29, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Nezu et al. (USP 6,265,194, priority to December 1997). See the alignments attached to the reference. Nezu et al. teach a kinase that is is different from SEQ ID NO : 2 by an insertion of approximately 60 amino acids at position 226 of SEQ ID NO : 2. Therefore, Nezu et al. teach a polynucleotide encoding biologically active fragments and immunogenically active fragments of SEQ ID NO: 2 (Claim 24). This polynucleotide comprises at least 60 contiguous nucleotides of SEQ ID NO: 9 (Claim 32). This polynucleotide was placed in vector PCOS (Example 7; Claim 27) and transformed into Mammalian cells (Example 9) or into E coli host cell DH10B (Example 10; Claim 28). The method for producing these proteins is taught in Example 9 (Claim 29).

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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October 23, 2002

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER